IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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| IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION | ) | MDL NO. 1203 |
| THIS DOCUMENT RELATES TO: | ) | |
| SHEILA BROWN, et al. | ) | |
| v. | ) | CIVIL ACTION NO. 99-20593 |
| AMERICAN HOME PRODUCTS CORPORATION | ) | 2:16 MD 1203 |

**MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9190**

Bartle, J. January 8, 2014

Randy G. Merrick ("Mr. Merrick" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Christine C. Merrick, Mr. Merrick's spouse, also has submitted a claim for derivative benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

Under the Settlement Agreement, only eligible claimants are entitled to Matrix Benefits. Generally, a claimant is considered eligible for Matrix Benefits if he or she is diagnosed with mild or greater aortic regurgitation and/or mitral regurgitation by an echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period.[4] See Settlement Agreement §§ IV.B.1.a. & I.22.

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3. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

4. See Settlement Agreement § IV.A.1.a. (Screening Program established under the Settlement Agreement).

In February, 2009, claimant submitted a completed Green Form to the Trust signed by his attesting physician, Robert W. Mackie, M.D. Based on an echocardiogram dated November 26, 2002, Dr. Mackie attested in Part II of claimant's Green Form that Mr. Merrick had severe aortic regurgitation, surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™, and ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise.[5] Based on such findings, claimant would be entitled to Matrix A-1, Level V[6] benefits in the amount of $720,625.[7]

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5. Dr. Mackie also attested that claimant suffered from an abnormal left atrial dimension, an abnormal left ventricular end-systolic dimension, a reduced ejection fraction in the range of 30% to 34%, New York Heart Association Functional Class I symptoms, and a left ventricular ejection fraction of < 40% at any time six months or later after the valvular repair or replacement surgery. These conditions are not at issue in this claim.

6. Under the Settlement Agreement, a claimant is entitled to Level V benefits if he or she qualifies for Level IV benefits and suffers from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. See Settlement Agreement § IV.B.2.C.(5)(d). The Trust concedes that claimant qualifies for Level IV benefits. Although the Trust contests whether claimant suffers from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise, given our disposition with respect to claimant's level of aortic regurgitation, we need not resolve this dispute.

7. Mr. Merrick previously was paid Matrix A-1, Level III benefits in the amount of $733,670 for a claim based on damage to his mitral valve. According to the Trust, if entitled to Matrix A-1, Level V benefits for a claim based on damage to his aortic valve, claimant would be entitled to Matrix Benefits in the amount of $1,454,295. The amount at issue, therefore, is the difference between the Matrix A-1, Level III benefits already

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In the report of claimant's echocardiogram, Dr. Mackie stated, "There is no aortic insufficiency." A handwritten note on the report states, "Echocardiogram Disc Reviewed on 5/7/2009. There is mild Aortic Valve insufficiency present on the [echocardiogram] of 11/26/02. This was missed and not reported on typed Report I generated on 11/26/02." Under the Settlement Agreement, mild or greater aortic regurgitation is present where the regurgitant jet height ("JH") in the parasternal long-axis view (or in the apical long-axis view, if the parasternal long-axis view is unavailable) is equal to or greater than ten percent (10%) of the left ventricular outflow tract height ("LVOTH"). See Settlement Agreement § I.22.

In June, 2009, the Trust forwarded the claim for review by Craig M. Oliner, M.D., one of its auditing cardiologists. In audit, Dr. Oliner determined that there was no reasonable medical basis for the attesting physician's representation that Mr. Merrick had severe aortic regurgitation. Specifically, Dr. Oliner explained, "There is no [aortic regurgitation] on the 11/26/02 [echocardiogram]."

Based on Dr. Oliner's finding, the Trust issued a post-audit determination denying Mr. Merrick's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit

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7. (...continued)
paid and the amount of the Matrix A-1, Level V benefits. See Settlement Agreement § IV.C.3.

Rules"), claimant contested this adverse determination.[8] In contest, Mr. Merrick submitted a letter from Dr. Mackie wherein he confirmed his earlier finding of mild aortic regurgitation on claimant's November 26, 2002 echocardiogram. Dr. Mackie explained that claimant's January 21, 2003 echocardiogram demonstrated mild to moderate aortic regurgitation and that it would be "nearly medically impossible" for Mr. Merrick's aortic regurgitation to advance to the mild to moderate level if there was less than mild demonstrated on the November 26, 2002 echocardiogram.

Although not required to do so, the Trust forwarded the claim for a second review by M. Michele Penkala, M.D., another of its auditing cardiologists. Dr. Penkala submitted a declaration in which she concluded that there was no reasonable medical basis for Dr. Mackie's representation that Mr. Merrick had at least mild aortic regurgitation. Dr. Penkala explained:

> 7. **There is no reasonable medical basis to find that Claimant had at least mild aortic regurgitation prior to January 3, 2002.** Both the 11/25/02 and the 11/26/02 studies show trace aortic regurgitation. While it is true that there is very significant aortic regurgitation (probably at least moderate) present on the initial

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8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. Merrick's claim.

> postoperative [transthoracic echocardiogram] done on 1/21/03, this is a VERY different-appearing highly eccentric [aortic insufficiency] jet that was not present previously. My impression is that the aortic valve was probably injured at the time of Claimant's 11/28/02 mitral valve replacement surgery (possibly via an errant stitch through the [noncoronary cusp]), which would explain the abnormality noted in the aortic valve leaflet at the time of the August 2007 [aortic valve replacement]/redo-[mitral valve replacement]. This [aortic insufficiency] jet on the 1/21/03 study is very prominent and very different in appearance and severity from the tiny jet noted on the earlier studies. Given the prominence of the [aortic insufficiency] jet on the 1/21/03 study, had it been present prior to the 1/21/03 study, such regurgitation would have been apparent in multiple views on the earlier studies. It is not. Hence, there is not a reasonable medical basis to find mild aortic regurgitation prior to January 3, 2003.

(Emphasis in original.)

The Trust then issued a final post-audit determination, again denying Mr. Merrick's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Mr. Merrick's claim should be paid. On April 9, 2010, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8456 (Apr. 9, 2010).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust informed the Special Master by letter dated July 6, 2010 that it did not intend to submit a reply. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[9] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met his burden of proving that there is a reasonable medical basis for the attesting physician's representation that he suffered from at least mild aortic regurgitation between the commencement of Diet Drug use and the end of the Screening Period. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the

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9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of his claim, Mr. Merrick argues that Dr. Penkala's opinion that his aortic regurgitation was the result of injury to the aortic valve during his mitral valve replacement surgery is conjecture. According to Mr. Merrick, there is a reasonable medical basis for Dr. Mackie's representation of mild aortic regurgitation prior to January 3, 2003 because: (1) the difference in appearance of the aortic jet before his mitral valve surgery and after his mitral valve surgery relates to the pressure being placed on his aortic valve by his "fully flailed" mitral valve, and (2) some aortic regurgitation existed on the November 26, 2002 that increased in severity with the passage of time requiring aortic valve replacement surgery.

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiograms and concluded that there was no reasonable medical basis for finding that Mr. Merrick had at least mild aortic regurgitation prior to the end of the Screening Period. Specifically, Dr. Abramson explained, in pertinent part:

In reviewing the echocardiogram from 11/25/02, there is possible evidence of trace aortic regurgitation seen only in the parasternal short-axis aortic valve view. There is a tiny pixel of red-yellow flow at the apposition of the aortic cusps during diastole which is visualized in two out of ten cardiac cycles in this view and may be interpreted as trace aortic regurgitation. Lack of confirmatory evidence of this diastolic flow in another view makes it difficult to interpret this intermittent flow as aortic regurgitation. In the parasternal long-axis, there is no evidence of aortic regurgitation. Sometimes the color flow from the severe mitral regurgitation seems to extend into the left ventricular outflow tract simply because we are viewing a 3-dimensional structure in 2 dimensions, but this abnormal flow never occurs during diastole. In the parasternal short-axis view, a color m-mode is performed which is usually performed to assess the severity of aortic regurgitation. There is blue flow above the high velocity mitral regurgitation jet, which if examined briefly, may be misinterpreted as aortic regurgitation. Upon close inspection, you can see that the blue color flow is representative of mitral inflow because the cursor is through the mitral valve, not the aortic valve. There is no aortic regurgitation visualized in the apical-3-chamber or apical-5-chamber views. There is no spectral Doppler evidence of aortic regurgitation. There are no measurements on the tape.

In reviewing the echocardiogram from 11/26/02, there is no evidence of aortic regurgitation on color flow imaging or spectral Doppler. On the parasternal long-axis there is a tiny flash of pixels occurring over the aortic valve during systole which cannot be aortic regurgitation, because aortic regurgitation is a diastolic flow. On the parasternal short-axis aortic valve view, there is no abnormal color flow during diastole. On the apical long-axis, there is significant flashing in the image due to the severe mitral regurgitation, but there is no abnormal diastolic flow emanating

> from the aortic valve. In the apical-5-chamber, there is bright blue flow in the left ventricular outflow tract during systole which represents a high stroke volume from the severe mitral regurgitation, but there is no abnormal diastolic flow. There is no spectral Doppler. There are no measurements performed by the technologist on the CD.
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> In summary, a reasonable echocardiographer would not interpret the severity of the aortic regurgitation on the echocardiogram of November 26, 2002 as severe. A reasonable echocardiographer would interpret the aortic regurgitation on the echocardiogram of November 25, 2002 as none or trace, but definitely less than mild. There is no reasonable medical basis for the physician completing the diet-drug recipient's claim form to state that Randy G. Merrick has at least mild aortic regurgitation on the 2002 echocardiograms.

In response to the Technical Advisor Report, claimant again argues that the existence of at least mild aortic regurgitation on his January 21, 2003 echocardiogram provides a reasonable medical basis for Dr. Mackie's representation that claimant had mild aortic regurgitation on the November 26, 2002 echocardiogram. In addition, claimant asserts that the cause of his medical condition is Diet Drugs rather than an "errant stitch."

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. Claimant does not adequately rebut the findings of the auditing cardiologists or the Technical Advisor. Claimant, we acknowledge, submitted a letter from Dr. Mackie explaining that claimant's November 26, 2002 echocardiogram demonstrated mild aortic

regurgitation. This conclusion was supported by the level of regurgitation demonstrated by claimant's January 21, 2003 echocardiogram. Nonetheless, Dr. Penkala reviewed claimant's November 25, 2002, November 26, 2002, and January 21, 2003 echocardiograms and determined there was no reasonable medical basis for finding that claimant had mild aortic regurgitation prior to the end of the Screening Period on January 3, 2003. With respect to claimant's January 21, 2003 ehcocardiogram, Dr. Penkala explained that the regurgitant jet on this echocardiogram was a "VERY different-appearing highly eccentric [aortic insufficiency] jet that was not present previously." Dr. Penkala opined that the different appearance was likely the result of the aortic valve being injured during claimant's November 28, 2002 mitral valve replacement surgery. Although claimant disputed Dr. Penkala's determination, he did not provide any opinion of a medical professional to support his criticism. In addition, Dr. Abramson reviewed claimant's November 25, 2002 and November 26, 2002 echocardiograms and determined that each of them demonstrated at most trace aortic regurgitation.[10] Mere disagreement with the auditing cardiologist and the Technical Advisor without identifying any specific errors by them is insufficient to meet a claimant's burden of proof.

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10. As noted in the Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue, trace aortic regurgitation is defined as a JH/LVOTH ratio less than 10%.

Finally, Mr. Merrick's assertion that he is entitled to Matrix Benefits because his condition is a result of his ingestion of Diet Drugs is erroneous. Causation is not at issue in resolving claims for Matrix Benefits. Rather, claimants are required to show that they meet the objective criteria set forth in the Settlement Agreement. As we previously concluded:

> Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only prove that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which that qualification occurred....

Mem. in Supp. of PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we noted:

> ... [I]ndividual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation.

Id. at 97. The Settlement Agreement unequivocally requires that claimant suffer from at least mild aortic regurgitation prior to the end of the Screening Period to be eligible for Matrix Benefits. We must apply the Settlement Agreement as written. Accordingly, claimant's assertion that his ingestion of Diet Drugs is the cause of his heart-related problems is not pertinent to the issue before the court.

For the foregoing reasons, we conclude that claimant has not met his burden of proving that there is a reasonable

medical basis for the attesting physician's representation that Mr. Merrick had at least mild aortic regurgitation between the commencement of Diet Drug use and the end of the Screening Period. Therefore, we will affirm the Trust's denial of Mr. Merrick's claim for Matrix A, Level V benefits and the related derivative claim submitted by his spouse.